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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,623	07/11/2005	Robert Johan Joseph Hageman	0012/73640/NHZ	7309

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,623	HAGEMAN ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 18-33* is/are pending in the application.

4a) Of the above claim(s) *26-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/09 has been entered.

Election/Restrictions

Applicant's election with traverse of group I invention (claims 1, 18-25) and election of caseinates from milk as the preferred species of protein (claim 1); guanidine acetic acid as the preferred species of glycocyamine (claim 1) ; folic acid as the preferred species of vitamin (claim 21); maltodextrin as the preferred species of food grade carbohydrate (claim 22); magnesium as the preferred species of mineral (claim 24); powder as the preferred form of composition (claim 25); and neurological disorders as the preferred form of disorder (claim 33) in the reply filed on 12/27/07 is acknowledged. The traversal arguments were answered in the office action dated 3/4/08.

Specification

1. The abstract of the disclosure is objected to because the abstract submitted is the first page of the WO 2004/000297 A1 (i.e., the published PCT/NL03/00448). Hence, this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Correction is required. See MPEP § 608.01(b).

2. The specification of the instant application also lacks the required format for presentation as provided in 37 CFR 1.77(b). The instant specification does not conform to the guidelines with sections under different titles such as:

(b) Cross-reference to related applications,

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. The specification comprises several tables and none of the table displays a number associated with the table to identify the table in the specification. It would be appropriate if the

tables are given identification numbers for the sake of clarity and for the sake of convenience to cite them in office actions and related correspondence.

4. The lengthy specification (22 pages) has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement(IDS)

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicants have filed an IDS on 10/17/05 that has been considered. However, the instant specification cites many patent and non-patent literature references throughout the disclosure (pages 3, 4, 7, 8, 11 and 16) that have not been submitted on an IDS.

Status of Pending Claims

Applicant's amendment to claims in the response filed on 6/29/09 has been acknowledged.

Claims 1 and 18-33 are pending.

Claims 2-17 have been canceled.

Claims 26-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/07.

Claims 1, 18-25 are examined on the merit.

Any objections and/or rejections made in the office action dated 12/24/08 and not specifically discussed in either the original or modified form here are considered withdrawn.

Withdrawn Rejections

Claim Rejections - 35 USC § 102(b)

Applicant's arguments, see pages 7-9, filed 6/29/09, with respect to the rejection(s) of claim(s) 1 and 18-25 under anticipation have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. A new ground(s) of rejection is made in view of applicant's amendments to claims 1 and 18.

Claim Rejections - 35 USC § 112, 1st Paragraph (New matter)

Applicant's arguments, see pages 7-9, filed 6/29/09, with respect to the rejection(s) of claim(s) 18 under 'New Matter' have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

New grounds of Rejections

Claim Objections

Claim 1 has been objected to because of the following informalities: Claim 1 recites "--" in defining limitations "a) and b)" in the claim. It is unclear as to use of the "--" to recite a limitation in the claim. The claim recited without the "--" spacer in the limitation would provide clarity to the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

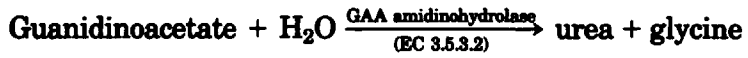
Claims 1 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 recites "b)--an energy metabolism precursor selected from glycocyamine (GA), **equivalents thereof**, and **mixtures thereof**" (emphasis added by office). The instant specification provides a very broad definition for the term "equivalents thereof" on page 12, lines 18-34, and page 13, lines 1-2. The definition provided on page 12 and in lines 24-29 is as follows: "**-ester and/or ether compounds** that can be metabolized to guanidino acetate in the gut or body, e.g., by hydrolysis, i.e., preferably esters of the carboxy group With lower organic acids and selected from esters of acetic acids, esters of propionic acid, esters of butyric acid, and mixtures thereof, Advantageously, these esters are stable in solution thus making them suitable for incorporation into liquids, in particular drinks or for enteral administration". The definition as

disclosed in the specification is non-limiting because the definition as disclosed does not identify the type (chemical or structural characteristics) of "**ester and/or ether compounds**" that would have the desired properties as defined and as required by the instant claims. Hence it is unclear from the claim as recited and from the disclosure as disclosed the definition of "equivalents thereof" since the chemical or structural characteristics of the compounds themselves are not adequately defined. Certainly, the term "mixtures thereof" will also be unclear when the chemical or structural characteristics of the "**ester and/or ether compounds**" are not apparent from the claims and from the instant disclosure.

2. Claim 1 recites that the nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine, equivalents thereof, and mixtures thereof, wherein the composition is **free of glycine**, or if glycine is present in the composition, the **weight ratio L-Serine to Glycine** is more than **2.7:1** as determined by hydrolysis" (emphasis added by office). The limitations as presented in the claims implies that the protein fraction used in the composition comprises of proteins and peptides that are rich in L-serine compared to Glycine, because, almost all protein from the natural source is made up of naturally occurring amino acids and hence invariably contains Glycine as one of the amino acids. The claim as presented is unclear as it does not identify the peptide or protein by name, the primary structural aspects of proteins or peptides in terms of SEQ ID NOs., or the source of such proteins or peptides that would have this desired requirement that the ratio of L-Serine to Glycine is more than 2.7:1 when Glycine is present in the composition. Moreover, the claim further recite that the determination of the ratio is made upon hydrolysis of the final

product or mixture. It should be noted that the composition comprises glycocyamine (GA). Glycocyamine is also known as guanidinoacetate, Guanidinoacetic acid; *N*-Amidinoglycine; *N*-Guanylglycine, etc., is a product of reaction between arginine and glycine. Shirokane, 1987, Clin. Chem., 33, 394-397 discloses that hydrolysis of Glycocyamine, i.e., guanidinoacetate yield urea and glycine (page 394, column 2, paragraph 1) according to the reaction:



This clearly illustrates the fact that it is unclear how the ratio of L-Serine:Glycine can be maintained at more than 2.7:1 in the composition when the hydrolysis of glycocyamine yields glycine. Even in the absence of free glycine in the composition, the glycine present in the protein fraction and the GA upon hydrolysis yields more glycine and hence the initial ratio of L-Serine:Glycine prior to hydrolysis would be vastly different from the ratio upon hydrolysis of the same composition due to the afore-illustrated hydrolysis of GA to glycine.

3. Instant claim 18 recites that the "**molar amount** of energy metabolism precursor lies within the range of from 0.1 to 10 times the excess of L-Serine versus Glycine". It is unclear from the limitation as recited the meaning of "molar amount" with regards to energy metabolism precursor, because, in claim 1, the applicants claim that the **weight ratio** L-Serine to Glycine is more than 2.7:1. It is unclear from the claims as recited how a relation between **weight ratio** of one variable i.e., **L-Serine:Glycine** is used in the determination of **molar amount** of another variable i.e., **GA** when the weight of **Glycine** in the composition itself would change upon hydrolysis of **GA** as illustrated above.

4. Applicants have amended the claims 1 and 18 using single set of brackets ("[]") as shown below:

[selected from the group consisting of L-serine, protein or peptides] in **claim 1** and

[minus] in **claim 18** to indicate that the text within the brackets has been 'deleted'.

According to MPEP section 714, under the subtitle "Markings to Show the Changes", the MPEP clearly states that "All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by strike-through (for deleted matter) or underlining (for added matter) with 2 exceptions: (1) for deletion of five or fewer consecutive characters, **double brackets** may be used **(e.g., [[eroor]])**".

It is unclear from the way the instant claims have been amended whether applicants are intending to 'delete' the subject matter within the brackets or simple using the bracket to indicate that the enclosed subject matter is independent of the sentence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

The claim as presented implies that the composition comprises a protein or a peptide, GA or equivalents and mixtures thereof and if glycine present in the composition, then the weight ratio of L-Serine : Glycine is more than 2.7:1 determined by the hydrolysis of the final product or mixture.

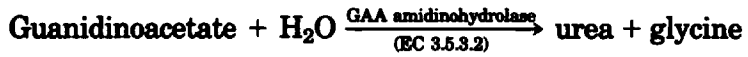
Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include:

a. Actual reduction to practice;
b. Disclosure of drawings or structural chemical formulas;
c. Sufficient relevant identifying characteristics such as:
    i. Complete structure,
    ii. Partial structure,
    iii. Physical and/or chemical properties or
    iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure;
d. Method of making the claimed invention;
e. Level of skill and knowledge in the art and
f. Predictability in the art.

While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

In the claims as presented, the claims recites that the source of L-Serine amino acid is protein fraction that contains proteins and peptides. The claim as recited does not identify the peptide or protein by name, the primary structural aspects of proteins or peptides in terms of

SEQ ID NOs., or the source of such proteins or peptides that would have this desired requirement that the ration of L-Serine to Glycine is more than 2.7:1 when Glycine is present in the composition. The claims as recited imply any protein or peptide can be used in the composition and the composition is a suitable composition if the **weight** ratio of L-serine:glycine is more than 2.7:1. Note that the claim as presented recites 'weight ratio' and not 'molar ratio'. In the absence of a specific protein or peptide recited in the instant claims, it should be noted all naturally occurring proteins and peptides comprises (contains) serine and glycine residues to varying degrees. Hence the weight ratio of serine:glycine in any and all of these proteins is to be determined after hydrolysis of the mixture that comprises GA. Glycocyamine is also known as guanidinoacetate, guanidinoacetic acid; *N*-Amidinoglycine; *N*-Guanylglycine, etc., is product of reaction between arginine and glycine. According to Shirokane, 1987, Clin. Chem., 33, 394-397 discloses that hydrolysis of Glycocyamine, i.e., guanidinoacetate yield urea and glycine (page 394, column 2, paragraph 1) according to the reaction:



This clearly illustrates the fact that it is unclear how the ratio of L-Serine:Glycine can be maintained at more than 2.7:1 in the composition when the hydrolysis of glycocyamine yields glycine. Even in the absence of free glycine in the composition, the glycine present in the protein fraction and the GA upon hydrolysis yields more glycine and hence the initial ratio of L-Serine:Glycine prior to hydrolysis in the composition would be vastly different from the ratio upon hydrolysis of the same composition due to the afore-illustrated hydrolysis of GA to glycine.

In the instant specification in a table on page 17, applicants disclose that the milk protein provides 0.48 g of L-serine and 0.16 g of glycine. The specification neither disclose the source of

the milk protein nor the primary structure of the protein (amino acid sequence). According to the information available from Swaisgood, 1993, J. Dairy Sci., 76, 3054-3061, casein (milk protein, source: cow) is a mixture of proteins comprising α_g1-CN, α_g2-CN, κ-Cn and β-CN (table 1, page 3056). The molar ratio of L-serine:glycine (shown in the parenthesis) differs in each of these proteins as follows: α_g1-CN (**8:9**), α_g2-CN (**6:2**), κ-Cn (**12:2**) and β-CN (**11:5**). The milk protein also comprises of 'phosphorylated serine' in the composition. Hence the ratio of L-serine:glycine differ from one milk protein to another as illustrated here. Hence the instant specification disclosing that casein that provides 0.48 g of L-serine and 0.16 g of glycine does not provide adequate written description to the instant invention (claims) as the source of the milk protein and the individual milk proteins contains L-serine and glycine residues to different extents.

Instant claim 18 recites that the "**molar amount** of energy metabolism precursor lies within the range of from 0.1 to 10 times the excess of L-Serine versus Glycine". It is unclear from the limitation as recited the meaning of "molar amount" with regards to energy metabolism precursor, because, in claim 1, the applicants claim that the **weight ratio** L-Serine to Glycine is more than 2.7:1. It is unclear from the claims as recited how a relation between **weight ratio** of one variable i.e., **L-Serine:Glycine** is used in the determination of **molar amount** of another variable i.e., **GA** when the weight of **Glycine** in the composition itself would change upon hydrolysis of **GA** as illustrated above.

Further the instant specification lacks a specific example wherein the final mixture of composition was subjected to hydrolysis and the weight ratio of L-serine: lysine was shown to be more than 2.7:1.

Hence, the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and one of ordinary skill in the art would not be able practice the invention commensurate with the scope of the claims as recited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by McCoy, 1956, American journal of Veterinary Research, 17, 90-97.

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

McCoy discloses a nutritional composition of low casein, supplemented with methionine and glycocyamine (page 91, column 1, bridging paragraph from page 90) for administering to dogs undergoing chemotherapy. The disclosure of McCoy that casein combined with glycocyamine was administered to dogs reads on the instant claim 1. The composition is free of

free glycine. Hence it is inherent that the instant composition meets the limitations of the instant claim that recites that the weight ration of L-serine:glycine is more than 2.7:1 as it teaches that the composition comprises of protein, glycocyamine and is free of free glycine amino acid. Since glycine is absent in the composition, it is inherent that it reads on the limitations of instant claim 18 as the amount of glycocyamine is 0.67% compared to 0.2% nitrogen from low casein component. MPEP section 2112 clearly states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer". Since the disclosure of McCoy teaches the composition of the instant invention, McCoy anticipates the instant invention as recited in claims 1 and 18.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1, 18 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Haik (US 6,727,285).

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

Haik discloses a composition of bovine serum albumin (BSA) a protein, glycocyamine (reads on instant claims 1 and 18) and methylglyoxal (an aldehyde) (reads on instant claim 23) in

a composition buffered with HEPES (Example 2 on column 14, and in Table 5 in column 29-30). The composition of Haik is free of free glycine amino acid. Hence it is inherent that the instant composition meets the limitations of the instant claim that recites that the weight ratio of L-serine:glycine is more than 2.7:1 as it teaches that the composition comprising of protein, glycocyamine and is free of free glycine amino acid. MPEP section 2112 clearly states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCoy, 1956, American journal of Veterinary Research, 17, 90-97 in view of Hageman (WO 99/03365).

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

McCoy discloses a nutritional composition of low casein, supplemented with methionine and glycocyamine (page 91, column 1, bridging paragraph from page 90) for administering to dogs undergoing chemotherapy. The disclosure of McCoy that casein combined with glycocyamine was administered to dogs reads on the instant claim 1. The composition is free of free glycine. Hence it is inherent that the instant composition meets the limitations of the instant claim that recites that the weight ration of L-serine:glycine is more than 2.7:1 as it teaches that the composition comprises of protein, glycocyamine and is free of free glycine amino acid. Since glycine is absent in the composition, it is inherent that it reads on the limitations of instant claim 18 as the amount of glycocyamine is 0.67% compared to 0.2% nitrogen from low casein component.

Although, McCoy discloses a composition of casein and glycocyamine, it does not disclose other ingredients such as vitamins (folic acid), carbohydrate (maltodextrin), mineral (magnesium), etc. The items in the parenthesis is the elected species in the instant invention.

Hageman discloses a nutritional composition comprising casein as the protein (example 4, page 13) (reads on instant claims 1 and 18). Maltodextrin and sucrose as sugar (example 4, page 13) (reads on instant claim 22). Folic acid as the vitamin (example 4, page 13) (reads on instant claim 21). Magnesium as the mineral (example 4, page 13) (reads on instant claim 24). 0.5 to 40 g of Creatine (claim 4, page 16) (reads on instant claim 19 and 20). This reads on the recited ratio for energy metabolism precursor to creatine of 0.2:5. Pyridoxal as the aldehyde (claim 1, page 16) (reads on instant claim 23). Hageman also discloses that the mixture is homogenized, pumped into a heat exchanger where the water is evaporated and resulting product spay-dried and packed into cans (page 12, lines 24 and 25). This reads on the instant claim 25 wherein the composition is in the powder form. It should be noted that the composition disclosed by Hageman is also free of free glycine.

It would have been obvious to one of ordinary skill in the art combine the teachings of McCoy and Hageman to arrive at the instant nutritional composition comprising protein containing L-serine, glycocyamine, carbohydrate, aldehyde, mineral, creatine and vitamins that is free of free glycine. McCoy discloses a nutritional composition comprising casein, glycocyamine and Hageman discloses a nutritional composition comprising casein, maltodextrin, folic acid, pyridoxal, creatine and magnesium. The compositions of both McCoy and Hageman are devoid of any free glycine. One of ordinary skill in the art would have been motivated to combine the teachings of McCoy and Hageman because, McCoy discloses that to combat toxicity of cancer drugs during cancer treatment the body depletes "labile protein stores" as studied in the dogs by McCoy. McCoy discloses that a nutritional formulation comprising low casein supplemented with methionine and glycocyamine reduced the excretion of urea nitrogen

thereby increasing the retention of body nitrogen (page 93, column 1, bridging paragraph from page 92). Hence incorporation of glycocyamine with casein is important in supplementing and retaining proteins in chemotherapy patients to overcome the toxic effects of the chemotherapy treatment which depletes proteins from the body. Therefore, one of ordinary skill in the art would incorporate glycocyamine into nutritional compositions comprising proteins and beneficial ingredients of Hageman to arrive at the instant invention. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Commonly owned and different inventive entities

Claims 1, 19, 21-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,544,547 ('547 patent) in view of McCoy, 1956, American journal of Veterinary Research, 17, 90-97.

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

'547 Patent discloses a food composition comprising of proteinaceous material (reads on instant claim 1), carbohydrates (reads on instant claim 22), folic acid (reads on instant claim 21), magnesium (reads on instant claim 24), creatine (reads on instant claim 19) and pyridoxal (reads on instant claim 23). '547 Patent does not disclose that free glycine was present in the composition.

'547 Patent does not disclose glycocyamine in the food composition.

McCoy discloses a nutritional composition comprising casein, glycocyamine that is free of free glycine.

It would have been obvious to one of ordinary skill in the art combine the teachings of McCoy and '547 Patent to arrive at the instant nutritional composition comprising protein containing L-serine, glycocyamine, carbohydrate, aldehyde, mineral, creatine and vitamins that is free of free glycine. McCoy discloses a nutritional composition comprising casein, glycocyamine and '547 Patent discloses a nutritional composition comprising casein, maltodextrin, folic acid, pyridoxal, creatine and magnesium. The compositions of both McCoy and '547 Patent are devoid of any free glycine. One of ordinary skill in the art would have been motivated to combine the teachings of McCoy and '547 Patent because, McCoy discloses that to combat toxicity of cancer drugs during cancer treatment the body depletes "labile protein stores" as studied in the dogs by McCoy. McCoy discloses that a nutritional formulation comprising low casein supplemented with methionine and glycocyamine reduced the excretion of urea nitrogen thereby increasing the retention of body nitrogen (page 93, column 1, bridging paragraph from page 92). Hence incorporation of glycocyamine with casein is important in supplementing and retaining proteins in chemotherapy patients to overcome the toxic effects of the chemotherapy treatment which depletes proteins from the body. Therefore, one of ordinary skill in the art would incorporate glycocyamine into nutritional compositions comprising proteins and beneficial ingredients of '547 Patent to arrive at the instant invention. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the

Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654